In the United States Court of Federal Claims

No. 08-185V
(Filed under seal April 8, 2014)
(Reissued April 24, 2014)[†]

JAMES HOLMES,	*	Vaccine Act motion for review; off-table case; tetanus and diphtheria vaccination; seizure disorder; use of statistical factors; treating physicians' opinions; expert witness credibility; causation-in-fact not established.
Petitioner,	*	
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES	*	
Respondent.	*	

Richard Gage, Cheyenne, Wyoming, for petitioner. *Donald Gerstein*, Cheyenne, Wyoming, of counsel.

Ryan D. Pyles, Trial Attorney, Torts Branch, Civil Division, Department of Justice, with whom were *Tony West*, Assistant Attorney General, *Mark W. Rogers*, Acting Director, *Vincent J. Matanoski*, Acting Deputy Director, and *Catharine E. Reeves*, Assistant Director, all of Washington, D.C., for respondent.

OPINION AND ORDER

WOLSKI, Judge.

Petitioner James Holmes has moved for a review of Special Master Denise K. Vowell's decision that he is not entitled to compensation under the National Vaccine Injury Compensation program, 42 U.S.C. §§ 300aa-10 *et seq*. (the Vaccine Act).[1] Petitioner alleges that a tetanus and diphtheria (Td) vaccination caused him to develop a seizure disorder. Petitioner raises three objections to the Special Master's decision to dismiss the petition. First, petitioner challenges

[†] Pursuant to Vaccine Rule 18(b) of the Rules of the United States Court of Federal Claims, this opinion was initially issued under seal to provide the parties the opportunity to object to the public disclosure of information contained within it. The parties have not requested redactions, and the opinion is reissued for publication with some minor, non-substantive corrections.

[1] Special Master Vowell has since been elevated to the position of Chief Special Master, but is referenced in this opinion using the position she held when issuing the decision under review.

the Special Master's reliance on statistical factors in determining causation. Second, petitioner argues the Special Master did not give the proper weight to treating physicians' opinions. Third, petitioner challenges the Special Master's determination of expert credibility. For the reasons that follow, the decision of the Special Master is **SUSTAINED**.

I. BACKGROUND

A. Vaccination and Subsequent Symptoms

Petitioner, James Edward Ivy Holmes II, was born on May 16, 1991. Petitioner's Exhibit (Pet'r's Ex.) 1 at 1. On August 17, 2005, petitioner had a yearly school physical as a fourteen-year-old in ninth grade. Pet'r's Ex. 6 at 1. According to the results of the physical, petitioner was "doing well, [with] no concerns," and he "denie[d] significant headaches, dizziness, fainting, motor or sensory losses." *Id.* at 1–2. As part of the physical, petitioner received a tetanus and diphtheria (Td) vaccination. *Id.* at 1, 4.

On the morning of the next day, August 18, petitioner had a brief seizure, and the emergency medical services (EMS) arrived to find him lying on the bed. Pet'r's Ex. 7 at 3. His older sister reported that while petitioner was sleeping she heard a "thump" and found him with his eyes rolled back in his head and with his feet moving back and forth, striking each other. Pet'r's Ex. 9 at 31, 43. His father had witnessed the tail end of the seizure. *Id.* at 31. The seizure was observed to last no longer than three minutes. *Id.* at 43. En route to the Swedish American Hospital, petitioner was alert but unable to speak. Pet'r's Ex. 7 at 3. According to the prehospital radio report, petitioner was warm and dry post-seizure, *id*. at 1, and the EMS personnel narrative stated that his skin color was normal and skin temperature was warm, though his temperature was not taken, *id*. at 2–3.

At the Swedish American Hospital emergency department, petitioner was examined by a primary care physician, Dr. Rose M. Stocker, and the emergency department recorded his oral temperature as 97.6 degrees. Pet'r's Ex. 9 at 28. The record also noted that petitioner had received immunizations the day before, and written under "Diagnosis and Procedure" was "seizure – s/p Td." *Id.* Petitioner was also examined by Dr. Ximena Llobet, to whom his parents reported that petitioner had no fevers or chills, and no complaints except for pain in his arm from the tetanus shot. *Id.* at 31. Doctor Llobet assessed the seizure as a generalized tonic-clonic seizure, noted that petitioner's temperature was 97.6 degrees, *id.*, and found him to be alert though still a "little bit postictal," *id.* at 32. Under "Impression," Dr. Llobet recorded "Seizure, status post tetanus shot." *Id.* Under "Ed Course/Medical Decision Making," Dr. Llobet wrote, "I had looked up the tetanus adverse reactions and one of them it listed is seizures." *Id.* She then stated that she called the Vaccine Adverse Event Reporting System, but instead of leaving a message gave Dr. Stocker the reporting system's phone number so she could do so. *Id.*

Petitioner did not have another seizure during two and one-half hours of observation in the emergency department, and he was released after being scheduled for an outpatient electroencephalogram (EEG). Pet'r's Ex. 9 at 32. He returned home and "did not have any headache, no nausea, no vomiting, no funny taste or smells in his mouth." *Id.* at 19. When petitioner fell asleep in the afternoon, however, his mother saw him experience a second seizure,

with "tonic-clonic jerks, eyes rolling back again," and foaming at the corner of his mouth.[2] *Id.* Petitioner's mother also described three to four minutes of "generalized shaking," followed by approximately twenty minute "episodes" where petitioner appeared dazed. *Id*. at 12. She said he felt warm, but did not take his temperature. *Id.* The EMS services reported that petitioner was postictal at the time of their arrival, and he was brought to the Swedish American Hospital emergency department at 3:45 p.m. Pet'r's Ex. 7 at 5.

In an emergency department record created at 4:00 p.m., petitioner was noted to have an oral temperature of 100 degrees and a rectal temperature of 99.9 degrees. Pet'r's Ex. 9 at 6. Under "triage note," one of the conditions listed was "[f]ever," and petitioner was given 650 mg of Tylenol and 750 mg of Dilantin. *Id.* The nursing care record confirmed both the rectal temperature of 99.9 degrees and Tylenol dosage, and also noted that he had a "swollen shoulder from vaccinations yesterday." *Id*. at 9–10. Doctor Anthony Schultz evaluated petitioner upon his arrival at the emergency department, noting that he "showed temperature 100 [degrees]" and had a rectal temperature of 99.9 degrees. *Id*. at 12. Doctor Schultz observed a "small inflammatory reaction at the site of the tetanus shot" which was not warm. *Id*. at 13. In his record, Dr. Schultz reported that he found no redness, axillary lymphadenitis, or axillary lymph node swelling. *Id.* Under the "Impression" portion of the record, Dr. Schultz wrote: "Seizure by history, most likely secondary to tetanus toxoid immunization." *Id.*

Subsequently, petitioner received an evaluation from Dr. Wen-Ho Yang, who recorded petitioner's temperature as 100 degrees. Pet'r's Ex. 9 at 20. Noting that petitioner had received a tetanus shot on his left deltoid the day before and reported soreness in his left arm, *id*. at 19, Dr. Yang observed that his left deltoid was "warm to touch, slightly indurated and tender to touch," *id*. at 20. Doctor Yang, however, did not observe any abscesses or areas of redness. *Id.* From petitioner's physical examination, Dr. Yang recorded the impression that "[g]iven his recent history of a tetanus vaccine, he could well have had a reaction towards the vaccine components, probably horse serum." *Id*. at 21.

A computed tomography (CT) scan for fractures and intracranial processes was negative. Pet'r's Ex. 9 at 21. Petitioner also received an echocardiogram, yielding results in the normal range. *Id*. at 26. In his discharge summary, Dr. Saurabh Vaish reported that petitioner did not have any seizures in the hospital and did not develop "any fevers, neck stiffness, nausea or vomiting," *id.* at 17–18, and he discharged petitioner with a final diagnosis of "new onset seizures." *Id.* at 17.

Petitioner went to neurologist Dr. Philip Miner for a follow-up neurological consultation on September 6, 2005. At this initial visit, Dr. Miner noted that petitioner had two generalized seizures and that he was "afebrile at the time." Pet'r's Ex. 8 at 1. Doctor Miner's assessment was that petitioner had "[s]econdarily generalized seizures of unclear etiology." *Id.* Petitioner's mother expressed the concern that he did not "look quite right" since he had been on the Dilantin, and Dr. Miner ordered a discontinuation of Dilantin and the beginning of treatment

[2] Petitioner's mother reported that the second seizure occurred around 1 p.m., Pet'r's Ex. 9 at 19, but the EMS narrative stated that a "Medical/Illness call was received at 15:29." Pet'r's Ex. 7 at 5.

with Depakote. *Id.* On September 15, 2005, a brain Magnetic Resonance Imaging (MRI) exam produced normal results, with no intracranial mass or other abnormalities. *Id.* at 4. At a visit to Dr. Miner on September 28, 2005, petitioner's mother reported no new seizures, but said petitioner seemed "very forgetful." *Id*. at 5. Doctor Miner also observed a macular-papular rash over petitioner's torso, neck, and extremities, and he prescribed Trileptal to replace Depakote. *Id.*

On October 7, 2005, petitioner experienced two seizures and went to the Swedish American Hospital emergency department at 9:45 a.m.[3] Pet'r's Ex. 9 at 56. These seizures occurred on the day he was to begin the Trileptal, after stopping the use of Dilantin and Depakote. *Id.* at 59. During a visit to Dr. Miner on November 10, 2005, Dr. Miner observed a macular rash over petitioner's entire torso, which had faded and apparently did not bother petitioner. Pet'r's Ex. 8 at 11. After assessing his other symptoms, Dr. Miner diagnosed petitioner with epilepsy.[4] *Id.* At a December 10, 2005 visit, Dr. Miner repeated his assessment of "[s]econdarily generalized epilepsy." *Id.* at 15.

Petitioner remained on Trileptal and did not have another seizure until May 14, 2006. On that day, petitioner had a full-body seizure in his sleep that lasted approximately two to three minutes, Pet'r's Ex. 9 at 83, 89, after failing to take his seizure medicine the day before, *id.* at 84. Doctor David E. Miller noted petitioner's history of seizures and headaches and concluded that he had an acute breakthrough seizure. *Id*. at 83–84. On May 5, 2007, petitioner experienced another seizure, after skipping two days of seizure medications. Pet'r's Ex. 12 at 3. At 4:15 p.m. on May 31, 2007, petitioner went to the emergency room again after having a full-body seizure of approximately two minutes, his second seizure of the day. *Id*. at 33.

B. The Petition and Hearing Before the Special Master

On March 18, 2008, when petitioner was still a minor, his mother, Christina Loudermilk, filed a petition for vaccine compensation on his behalf. Pet. at 1.[5] The petition alleged that petitioner's seizures and neurologic injuries were caused by his Td vaccination on August 17, 2005. *Id*. Attached to the petition were various medical records for petitioner such as petitioner's prenatal and birth records, vaccination records, newborn records, and pediatric records; the ambulance reports from petitioner's seizure incidents; petitioner's hospital records, and the neurology report from Dr. Miner. *See id.*, Exs. 1–9.

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[3] The date was mistakenly written as October 11 in Dr. Miner's record of petitioner's visit on November 10, 2005. Pet'r's Ex. 8 at 11.

[4] In a December 18, 2006 record, Dr. Miner recorded the assessment of "[e]ncephalopathy," Pet'r's Ex. 8 at 26, Pet'r's Ex. 11 at 10, which is reported in only one subsequent record. *See* Pet'r's Ex. 11 at 15. The other records concern primarily epilepsy. *See* Pet'r's Ex. 11 at 13, 18, 21, 24, 26, 28.

[5] The case was recaptioned as brought by James Holmes once he reached the age of majority. *See* Order (July 6, 2010).

Within two months, petitioner also filed a neuropsychological evaluation from a clinical pediatric neuropsychologist, Lisa Mottram, Ph.D. Pet'r's Ex. 10. The report included results from a psychoeducational evaluation, showing cognitive deficits such as slowed mental processing speed, verbal memory and learning difficulties, and working memory difficulties. *Id.* at 5–6. The report also suggested that these deficits were the result of petitioner's seizure disorder. *Id*. at 5.

1. The Expert Witnesses' Reports

In addition to more of his medical records, *see* Pet'r's Exs. 11–13, petitioner also filed expert reports from Dr. Marcel Kinsbourne, scientific articles, and information on tetanus toxoid. *See* Pet'r's Exs. 14–20.[6] In his initial expert report, Dr. Kinsbourne posited that the Td vaccination triggered complex febrile seizures that caused petitioner's epilepsy, resulting in cognitive impairments. Pet'r's Ex. 14 at 3. According to Dr. Kinsbourne, petitioner's 99.9 degree temperature after the second seizure represented a low-grade fever, and the "vigorous local inflammatory reaction at the vaccination site indicate[d] the local presence of an intense immune reaction, involving proinflammatory cytokines." *Id.* at 2. Doctor Kinsbourne wrote that the cytokines "could enter the blood stream and cause seizures, through the intermediary effect of fever and/or by directly provoking epileptogenesis." *Id.* at 2–3. Citing drug evaluations issued by Micromedex and the opinions of petitioner's treating physicians, Dr. Kinsbourne attributed the seizures to the tetanus vaccination and argued that petitioner's medical records did not reveal a "potential alternative causal or provoking event." *Id.* at 3. In support of his argument, Dr. Kinsbourne cited a 1987 medical journal article (the Annegers study)[7] that found that the risk of epilepsy was greater after complex than simple febrile seizures. Pet'r's Ex. 14 at 3; *see* Pet'r's Ex. 15 at 1 ("The risk ranged from 2.4 percent among children with simple febrile convulsions to 6 to 8 percent among children with a single complex feature -- i.e., focal or prolonged seizures or repeated episodes of febrile convulsions with the same illness. For children with any two of the complex features, the risk was 17 to 22 percent.").

Respondent's report was filed on September 4, 2009, supported by an expert report from Dr. Shlomo Shinnar and copies of medical and scientific literature filed on a compact disc. *See* Resp't's Rep., Exs. A– B; Resp't's Notice of Intent to File on Compact Disc (Sep. 4, 2009), Docket No. 31; Resp't's Exs. A1–A26. Relying on Dr. Shinnar's report, respondent challenged Dr. Kinsbourne's opinion and argued that petitioner failed to establish that the Td vaccination was causally connected to a seizure disorder or to lasting neurological decline. Resp't's Rep. at 6–7. In his report, Dr. Shinnar disagreed with Dr. Kinsbourne's opinion that petitioner had experienced complex febrile seizures, noting that the minimum threshold for a fever in the relevant studies was usually 101 degrees. Resp't's Ex. A at 4. Though Dr. Shinnar agreed that cytokines could produce seizures, he explained that an association with a febrile illness required the actual presence of a fever. *Id.* at 5. Doctor Shinnar further noted that various studies of

[6] The qualifications and experience of Dr. Kinsbourne and of respondent's expert, Dr. Shinnar, are detailed below in the accounts of their respective testimony.

[7] *See* Pet'r's Ex. 15 (John F. Annegers et al., *Factors Prognostic of Unprovoked Seizures after Febrile Convulsions*, 316 NEW ENGL. J. MED. 493-98 (1987)).

febrile seizures considered children up to age twelve at most (and usually under age ten), but petitioner was age fourteen at the time of his first two seizures. *Id*. The usual latency to develop epilepsy was eight to eleven years after prolonged febrile seizures, Dr. Shinnar argued, and petitioner's second set of seizures were only two months after his vaccination. *Id.* At age fourteen, Dr. Shinnar noted, petitioner was at a common age for the development of seizure disorders, and a significant number of epilepsy syndromes begin in adolescence. *Id.* at 6. Doctor Shinnar concluded that petitioner's seizures were not the result of a vaccine-related injury and did not meet the criteria for complex febrile seizures. *Id.* at 7.

Doctor Kinsbourne responded with a "supplementary report" filed on November 23, 2009. Pet'r's Ex. 18. He again referenced the Micromedex evaluations as showing that tetanus toxoid can cause seizures, and alleged, with no citation, that petitioner's "temperature was recorded as 100 degrees axillary" in the emergency room the day of his initial seizures. *Id*. at 1. This temperature would "correspond[] to an oral temperature of 101 degrees," and would thus "meet Dr. Shinnar's epidemiologically based arbitrary cutoff point for fever." *Id*. Doctor Kinsbourne contended that this fever, as well as petitioner's "'small inflammatory reaction' at the vaccination site," which included a "'swollen left shoulder,'" evidenced "ample cytokine production" to support his causation theory. *Id*. at 2 (quoting Pet'r's Ex. 9 at 9, 13). He recounted the medical records in which three treating physicians associated the initial seizures with the tetanus vaccine. Pet'r's Ex. 18 at 2 (citing Pet'r's Ex. 9 at 13, 21, 32). And he criticized Dr. Shinnar for failing to "explain the biological mechanism by which" the vaccine could result in seizures when recipients are age ten or twelve, but cease doing so for fourteen-year-olds. *Id*. Petitioner's expert also pointed to medical records supporting the diagnosis of encephalopathy, and to the Micromedex evaluations noting reported associations between encephalopathy and tetanus toxoid. *Id*. (citing Pet'r's Ex. 16 at 4, Ex. 8 at 26, Ex. 11 at 10, Ex. 10 at 5). He disagreed with Dr. Shinnar's interpretation of the neuropsychological testing report written by Dr. Mottram, and noted that respondent's expert "did not offer a specific alternative causation." *Id.* at 3.

Doctor Shinnar replied in a "supplemental report," filed on January 27, 2010. Resp't's Ex. C. He criticized the Micromedex document for not distinguishing between young children, for whom seizures are unquestionably associated with tetanus vaccines, and older children or adolescents, for whom no data associates the two. *Id*. at 1. He cites "the Academy of Pediatrics Red Book[,] which is an authoritative source and does distinguish between those reactions seen in children and those seen in adolescents." *Id*.; *see also* Resp't's Ex. D. Doctor Shinnar disputed that petitioner had a fever when he suffered the initial seizures, and reiterated that a person as old as petitioner was at the time could not have a febrile seizure. Resp't's Ex. C at 2. He stressed that no literature supports Dr. Kinsbourne's "claim of a complex febrile seizure as a result of [Td] immunization occurring in a 14 year old adolescent." *Id*. at 3.

2. The Special Master's Hearing

On June 30, 2010, Special Master Vowell held a hearing on the petition for compensation. Doctor Kinsbourne testified as the expert for petitioner, and Dr. Shinnar did so on behalf of the Secretary. Doctor Marcel Kinsbourne completed his undergraduate and medical education at Oxford University in England, where he also took the examination for Membership

of the Royal College of Physicians and lectured in experimental and neurological psychology. Sp. Mstr. Tr. at 6–7. In 1967, Dr. Kinsbourne became a professor of neurology and psychology and the chief of the Division of Child Neurology at Duke University. *Id*. at 7–8. He then became a senior staff physician at the Hospital of Sick Children in Toronto and a professor at the University of Toronto, in 1974. *Id.* at 8. In 1980, after twenty-five years of a general neurology practice, Dr. Kinsbourne specialized in developmental neurological disorders, such as behavioral disorders, cognitive disorders, and mental retardation. *Id.* He became a chief of the division of behavioral neurology at the Eunice Kennedy Shriver Center in Boston and, in 1995, became a professor in the psychology department at the New School, teaching and conducting research with a laboratory of eight-to-ten graduate students in psychology. *Id.* at 9. Doctor Kinsbourne has published extensively in medical and scientific journals, with his more recent work concerning autism and attention-deficit/hyperactivity disorder. *Id.* at 10.

Doctor Kinsbourne began his testimony with a focus on the tetanus toxoid component of the Td vaccination. Sp. Mstr. Tr. at 12. Referring to a drug evaluations document from Micromedex Healthcare, *see* Pet'r's Ex. 16, Dr. Kinsbourne identified convulsions and encephalopathy as some of the neurological complications that result from tetanus toxoid, as well as the general side effect of seizures. Sp. Mstr. Tr. at 13. Doctor Kinsbourne next turned to petitioner's medical records from the day of his first two seizures, noting the opinions of treating physicians Drs. Schultz, Yang, and Llobet that petitioner's seizures were related to his Td vaccination. *Id*. at 15–17. Pertaining to the temporal relationship prong of *Althen*, Dr. Kinsbourne next testified that a seizure occurring within 24 hours of the Td vaccination "wouldn't have to be within that time frame, but it would typically be." *Id.* at 18.

Doctor Kinsbourne submitted that petitioner's "swollen shoulder from vaccination" was a "local inflammation caused by the vaccination mediated by what are called pro-inflammatory cytokines." Sp. Mstr. Tr. at 20. In response to the Special Master's question about the term "mediated," Dr. Kinsbourne clarified that "[t]he chemistry is more complex" but "cytokines are an essential part of [the inflammation]." *Id.* Doctor Kinsbourne testified that the cytokine Interleukin One beta (IL-1 beta) was known to cause fever and seizures, and that a study had shown that IL-1 beta could cause seizures without the presence of fever. *Id*. at 21–23 (citing Resp't's Ex. A24). Though Dr. Kinsbourne conceded that the study was based on rats and did not reflect temperatures in humans, he argued that the causal link between IL-1 beta and seizures had been "documented massively." *Id.* at 23–24. Referring to medical records noting that petitioner was "warm" at the time of his first two seizures, Dr. Kinsbourne explained that it was "not uncommon" for someone's temperature to fluctuate. *Id.* at 28, 31, 33.

Doctor Kinsbourne then addressed the question of whether petitioner's two seizures on August 18, 2005, were focal seizures. He interpreted the EMS record notation, "[e]n[]route p[atien]t alert but unable to speak to us," Pet'r's Ex. 7 at 3, to mean that petitioner's first seizure originated from the left hemisphere of the brain, where it affected speech functions. Sp. Mstr. Tr. at 33–34. Doctor Kinsbourne reconciled this interpretation with observations of convulsions on both sides of petitioner's body by explaining that petitioner could have experienced a focal seizure that "had gotten to the bilateral stage" when it was witnessed by his family. *Id.* at 36–37. Regarding the second seizure, Dr. Kinsbourne noted that petitioner "looked up and rightward" at

the onset of that seizure, indicating "excessive neurologic activity in the left hemisphere." *Id.* at 39–40.

A complex febrile seizure, Dr. Kinsbourne explained, is characterized by three features: "partial onset, which is the same as focal"; prolonged duration of more than ten or fifteen minutes; and multiple seizures in "a single illness episode generally in a 24 hour period." Sp. Mstr. Tr. at 48–49. Citing the Annegers study, Dr. Kinsbourne stated that children with "a single complex feature" have a six to eight percent risk of unprovoked seizures after febrile convulsions and children with "any two of those three features" had a seventeen to twenty-two percent risk. *Id.* at 51. For children with all three features, the risk was forty-nine percent, though Dr. Kinsbourne noted that he could not establish that petitioner's seizures were sufficiently prolonged. *Id.* When asked if he attributed "the onsetting then subsequent seizure disorder of [petitioner] to his tetanus vaccination," Dr. Kinsbourne replied that he did. *Id.* at 53. In Dr. Kinsbourne's opinion, petitioner "suffered a brain injury consequence on the series of events unleashed by the vaccination and the febrile complex seizure which followed." *Id.* at 54.

On cross-examination, Dr. Kinsbourne was asked about his experience clinically treating patients with seizure disorders (which ceased around 1980); about the subject matter of his publications (none of which was on seizures or epilepsy); and about the percentage of his income which was due to expert testimony (which was about fifty percent, most of which came from vaccine cases). Sp. Mstr. Tr. at 55–57. Turning to the substance of his expert opinion, Dr. Kinsbourne stated that his opinion was "dependent on [petitioner] having had a complex febrile seizure." *Id.* at 57. When asked if he meant that, without the presence of a fever, the vaccine could not have caused petitioner's injury, Dr. Kinsbourne replied: "I wouldn't dream of saying that without fever the vaccine wouldn't have caused it because I don't know that. Might have caused it, but I'm not presenting that case to the court at this time." *Id.* at 57–58. He clarified that "the opinion [he was] presenting is predicated on" petitioner's first two seizures "meeting with the definition of febrile complex seizure." *Id.* at 58.

In the context of populations in epidemiological studies, Dr. Kinsbourne noted that "the lower level for recognized fever would be 100.4 degrees for rectal temperature," 99.4 degrees for oral temperature, and 98.4 degrees for axillary temperature. Sp. Mstr. Tr. at 59–60. In his opinion, however, there was a continuum with "enormous variation" of elevated temperatures at which people would be susceptible to seizures. *Id.* at 60. Noting the variations in a person's temperature throughout the day, Dr. Kinsbourne stated that temperatures tend to be higher in the afternoon and lower in the early morning and evening. *Id.* at 61. He agreed with respondent's counsel that petitioner's oral temperature of 97.6 degrees after the first seizure was not febrile. *Id.* at 62. Regarding petitioner's temperature at the time of the second seizure, Dr. Kinsbourne had claimed in his report that petitioner had an axillary temperature of 100 degrees. *Id.* at 63. After reviewing a copy of the medical record, Dr. Kinsbourne conceded that he had mistaken an oral temperature of 100 degrees for axillary temperature. *Id.* Doctor Kinsbourne nonetheless maintained his opinion that petitioner had experienced febrile seizures, *id.* at 65, and that temperature readings taken after the seizure would not reflect temperature during the seizure, *id.* at 66.

Subsequently, the cross-examination focused on whether petitioner would be considered a child and part of the population for which there were epidemiological studies. Though Dr. Kinsbourne agreed with respondent's counsel that petitioner "was an adolescent at age 14," he also stated that "child" would encompass an age range "certainly to age 15 and probably to age 18." Sp. Mstr. Tr. at 67–68. Referring to respondent's exhibit D, "the Red Book," respondent counsel asked if it would indicate that seizures from a tetanus vaccination were "not an issue in the adolescent population." *Id.* at 70. Doctor Kinsbourne responded that "the idea that it would be less of an issue in adolescents than it is in other ages of childhood I think is actually absurd," noting that seizure disorders tend to emerge during adolescence. *Id.*

At the end of cross-examination, the Special Master asked Dr. Kinsbourne to explain petitioner's exhibit 16, a document from a Micromedex service subscription that described "important aspects" of the tetanus toxoid vaccine. Sp. Mstr. Tr. at 73–74. Doctor Kinsbourne testified that, to his knowledge, the tetanus toxoid was "no different" from the tetanus in the Td vaccination. *Id.* at 74. He agreed with the Special Master that horse serum was no longer used in tetanus toxoid and that one of petitioner's treating physicians, Dr. Yang, was incorrect in referring to horse serum as a possible cause of petitioner's seizures. *Id.* at 75–76.

Upon redirect examination by petitioner's counsel and cross-examination by respondent's counsel, Dr. Kinsbourne repeated his assessment that the EMS record describing petitioner as "warm" referred to elevated temperatures. Sp. Mstr. Tr. at 98. In response to questioning by respondent's counsel and the Special Master, Dr. Kinsbourne also clarified his opinion of the difference between seizure disorder in infants, adolescents, and adults. *Id.* at 106. In his opinion, the probability of complex febrile seizures fluctuates with age but did not imply a qualitative difference. *Id.* at 107–08. Doctor Kinsbourne stated that he "[did]n't see the big difference between 10[-] and 14-year-olds," but he "can't really answer [the] question" of whether there was a significant difference in probability of unprovoked seizures. *Id.* at 109–10.

Doctor Shlomo Shinnar is a pediatric neurologist working at Montefiore Medical Center in New York City. Sp. Mstr. Tr. at 120. He earned his undergraduate degree at Columbia College and received both an M.D. and a Ph.D. in neuroscience from the Albert Einstein College of Medicine. *Id.* Doctor Shinnar is a professor of neuroscience research and also the director of comprehensive epilepsy management at Montefiore. *Id.* at 121. He particularly specializes in treating children with seizure disorders and divides his time between teaching, research, and personally treating patients. *Id.* As the senior neurologist for the Montefiore clinic, *id.* at 122–23, Dr. Shinnar's patients reflect a broad range of neurological disorders, with about two-thirds of them having epilepsy and many having suffered febrile seizures. *Id.* at 122. Though his patients usually range in age from newborn to twenty-one years, he typically follows his seizure patients into their adulthoods. *Id.* at 123. Doctor Shinnar has published over 150 peer-reviewed papers, over 100 chapters of review articles, and over 250 abstracts. *Id.* at 122. The majority of his publications have focused on seizures, with many on febrile seizures in particular. *Id.*

Doctor Shinnar testified that in his opinion the Td vaccination petitioner received had no causal relationship to petitioner's first two seizures on August 18, 2005, or to petitioner's subsequent epilepsy. Sp. Mstr. Tr. at 124–25. Doctor Shinnar explained that his main disagreement with Dr. Kinsbourne's assessment that petitioner suffered complex febrile seizures

was that the evidence did not show that petitioner's seizures fit the definition of febrile. *Id.* at 126. In support of his opinion, he referenced scientific studies and medical literature which reported that febrile seizures rarely began after the age of seven years (only 1–2 percent of cases), and noted that his research discovered only one child as old as nine years. *Id.* at 127–29. He testified that the overwhelming majority of children (85 to 90 percent) who suffered febrile seizures were younger than three years old, *id.* at 128, with a median age of eighteen months. *Id.* at 129. According to Dr. Shinnar, the tail end of an exponential distribution may rarely extend to an eight- or nine-year-old, but not to older children. *Id.*

In further support of his opinion, Dr. Shinnar testified that febrile seizures by definition occur in the context of a febrile illness which "implies that you have a sustained temperature . . . that could take weeks or many days," and there is no evidence that petitioner had such an illness. *Id.* at 135; *see id.* at 146. At the time of the initial seizure, the EMS report stated that petitioner's skin temperature was warm, *see* Pet'r's Ex. 7 at 2–3, but the emergency room report recorded his temperature as 97.6 degrees. *See* Pet'r's Ex. 9 at 28. Doctor Shinnar testified that "warm skin is a completely unreliable measure of temperature," *id.* at 137, and that the recorded temperature would have revealed a fever even after the seizure if the seizure had occurred in the context of a febrile illness. *Id.* at 134–35; *see id.* at 180. Petitioner's highest recorded temperature was 100 degrees, which Dr. Shinnar argued was below febrile and would be too low to cause any child to suffer a seizure (much less a fourteen-year-old, who is beyond the age for which fever may provoke a seizure). *Id.* at 133–34; *see id.* at 147. Thus, because of petitioner's age and because there was no evidence of a fever or febrile illness, Dr. Shinnar concluded petitioner did not have febrile seizures. *Id.* at 136.

Doctor Shinnar disagreed with Dr. Kinsbourne's suggestion that cytokines released by the vaccine caused petitioner to have a fever. While Dr. Shinnar acknowledged that the IL-1 beta cytokine was typically associated with redness and swelling around a wound, he contended that one could not infer from mere swelling that a fever had been induced --- the latter required enough cytokines to cause a systemic febrile reaction, which is evidenced by the fever itself. Sp. Mstr. Tr. at 143–45, 180. He also stated that a person must be in "the age of susceptibility" for the IL-1 to cause a fever that would result in a seizure, and that age fourteen is not in that range. *Id.* at 147.

Doctor Shinnar further testified that in his opinion petitioner's two seizures on August 18 did not result in his epilepsy and would not necessarily have "adversely impact[ed] [his] future course" because such seizures do not increase a person's risk for having further seizures or developing epilepsy. Sp. Mstr. Tr. at 149–51. According to Dr. Shinnar, a seizure would have to be prolonged for thirty minutes or more in order to cause a brain injury which could then result in epilepsy. *Id.* at 153; *see id.* at 155. Whether febrile or not, the duration of the seizure is what causes lasting injury to the brain, he explained, and seizures as brief as petitioner's initial ones would not cause epilepsy. *Id.* at 197–201. Additionally, Dr. Shinnar opined that it was not epilepsy but rather the medication petitioner was taking that caused the latter's cognitive impairment such as sleepiness and memory loss. *Id.* at 163–64. During cross-examination by petitioner's counsel, Dr. Shinnar repeated his opinion that petitioner probably had an underlying seizure disorder before August 18, 2005, which had not previously been manifest. *Id.* at 174–77.

He did not think the vaccination caused the epilepsy, and noted that "unclear etiology is the rule for two[-]thirds of child onset epilepsy." *Id.* at 177.

C. The Special Master's Decision Denying Compensation

On April 26, 2011, the Special Master issued a decision denying compensation, finding that petitioner failed to establish that the vaccination caused his injury. *Holmes v. Sec'y of HHS*, No. 08-185V, 2011 WL 2600612, at *1–2 (Sp. Mstr. April 26, 2011). The Special Master based this conclusion on "problems with the factual and medical underpinnings of the opinions" of petitioner's expert, whom the Special Master found less persuasive than respondent's expert. *Id.* at *2.

The Special Master identified the primary factual dispute to have been whether petitioner's two initial seizures the day after his Td vaccination were complex febrile seizures. *Id.* at *8. Petitioner had the first seizure the morning of August 18, 2005, and while being treated at the Swedish American Hospital emergency department his temperature was recorded to be 97.6 degrees. *Id.* at *6–7. After his release from the hospital, petitioner had another seizure later that afternoon. The emergency department recorded a rectal temperature of 99.9 degrees and oral temperature of 100 degrees fifteen minutes after his arrival. *Id.* at *7.

In Dr. Kinsbourne's opinion, petitioner had a fever at the times of both initial seizures, thus satisfying the criteria for complex febrile seizures. *Holmes*, 2011 WL 2600612, at *8. Doctor Kinsbourne posited that the vaccine caused an inflammation at the injection site, Sp. Mstr. Tr. at 20, which led to the release of the cytokine IL-1 beta, Sp. Mstr. Tr. at 21. According to Dr. Kinsbourne, the presence of IL-1 beta provoked complex febrile seizures that caused petitioner's epilepsy. *Holmes*, 2011 WL 2600612, at *14–15.

The Special Master found, however, that petitioner's expert was mistaken in believing that petitioner's August 18, 2005 seizures were febrile. *Holmes*, 2011 WL 2600612, at *8–10. Concerning the first seizure, Dr. Kinsbourne in his initial report found the presence of a fever based on the ambulance record describing petitioner's temperature as warm, and his belief that petitioner's mother stated petitioner "felt hot" during this seizure. *See id.*, at *9; Pet'r's Ex. 14 at 1–2. But the Special Master noted that "[t]he evidence indicates that [petitioner's mother] was not at home at the time of the first seizure." *Holmes*, 2011 WL 2600612, at *9 (citing Pet'r's Ex. 9 at 31 and Sp. Mstr. Tr. at 27–28). In his supplementary report, after citing the ambulance record corresponding to the first seizure, Dr. Kinsbourne reports that petitioner's axillary temperature was recorded to be 100 degrees in the emergency department, and cites hospital records which relate to the second seizure. *See* Pet'r's Ex. 18 at 1. The Special Master noted that the records for the second seizure cannot be the basis for a finding that petitioner had a fever during his first seizure, and that petitioner's expert failed to account for the petitioner's temperature of 97.6 degrees, recorded in the emergency room after the first seizure (which Dr. Kinsbourne conceded was a normal temperature). *Holmes*, 2011 WL 2600612, at *9 (citing Sp. Mstr. Tr. at 62). She found "no reliable evidence that [petitioner] was febrile at the time of his initial seizure," as skin feeling warm to the touch is relative, inaccurate, and not necessarily indicative of a fever. *Id*. (citing Pet'r's Ex. 19 at 1; Sp. Mstr. Tr. at 137–38; Pet'r's Ex. 7 at 1, 3). Moreover, Dr. Llobet's report of the emergency room examination of petitioner after his first

seizure noted both that his temperature was 97.6 degrees and that his skin was "warm and dry," further indicating that "'warm' as applied to [petitioner] does not appear to refer to fever." *Id.* (citing Pet'r's Ex. 9 at 31–32).[8]

Regarding petitioner's second seizure, the Special Master noted that although the emergency room record indicated that petitioner had a fever, neither the emergency room physician nor the treating physician diagnosed a febrile seizure, and the latter recorded that petitioner's second seizure was not preceded by a fever. *Holmes*, 2011 WL 2600612, at *9 (citing Pet'r's Ex. 9 at 12, 17–19). Doctor Kinsbourne had misread a medical record, which reported an oral temperature of 100°, as reporting an axillary temperature, and thus erroneously concluded that this corresponded to an oral temperature of 101°. *Id.* at *9–10 (citing Pet'r's Ex. 9 at 6; Pet'r's Ex. 18 at 1; Sp. Mstr. Tr. at 63–64). The actual reading, and the rectal temperature of 99.9° also taken during the second emergency room visit, were below the threshold used to define febrile seizures in most studies. *Id.* at *10.[9] Based on the medical records, the Special Master found that petitioner "had a slightly elevated temperature *after* his second seizure," and concluded "that the slight elevation in his temperature was not indicative of a febrile illness." *Id.* In sum, the Special Master "found no evidence that petitioner had a fever at the time of his initial seizure, and, at best, only a slight fever *after* his second seizure." *Id.* at *14.

Although Dr. Kinsbourne's opinion could have been rejected merely because he misread the medical records concerning petitioner's temperature, *Holmes*, 2011 WL 2600612, at *16 (citing *Perreira v. Sec'y of Dep't of HHS*, 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994)), the Special Master explained in detail why she rejected that opinion in favor of Dr. Shinnar's opinion that petitioner's symptoms did not meet the criteria for complex febrile seizures. *Id.* at *16–20. There was no evidence of fever high enough to cause a febrile seizure, or of any febrile illness. *Id.* at *17. Moreover, the Special Master was persuaded by Dr. Shinnar's testimony that febrile seizures occurred in childhood rather than adolescence, based on Dr. Shinnar's own research and another scientific study. *Id.* (citing Sp. Mstr. Tr. at 127–28, 132–33; Resp't's Ex. A21 at 495). In particular, 99% of children in febrile seizure studies were under seven years of age, and the oldest children with febrile seizures whom Dr. Shinnar had studied were nine and twelve years old. *Id.* (citing Sp. Mstr. Tr. at 127–28, 132–33).

The Special Master also found Dr. Shinnar's testimony in other areas to be "compelling" and "undercutting petitioner's cause-in-fact case." *Holmes*, 2011 WL 2600612, at *18. She discussed Dr. Shinnar's explanations that the Micromedex evaluations would not establish causation regarding illnesses that are not rare, and might have been based on the experiences of very young children. *Id.* (citing Pet'r's Ex. 16; Sp. Mstr. Tr. at 139–42, 198–201). She noted his testimony that febrile seizures would need to exceed thirty minutes in length to cause epilepsy,

[8] The Special Master also noted that petitioner "denied having fever or chills," and that "the skin temperature assessment was made on an August day in Chicago." *Holmes*, 2011 WL 2600612, at *9 (citing Pet'r's Ex. 9 at 31; Sp. Mstr. Tr. at 82–83).

[9] Moreover, "[t]he lowest temperature used in any study of febrile seizures and their sequelae is 100.4°, a higher temperature than any that [petitioner] experienced." *Holmes*, 2011 WL 2600612, at *17 (citing Sp. Mstr. Tr. at 133–34).

and that this would be temporal lobe epilepsy --- and that petitioner exhibited neither. *Id*. (citing Sp. Mstr. Tr. at 51–52, 190–91, 197–201). Though Dr. Shinnar acknowledged that sufficient quantities of IL-1 beta could cause fever and seizures, larger quantities of IL-1 beta are needed to produce fever in an adolescent, and the inflammatory reaction at the vaccination site in petitioner's case was insufficient to demonstrate such a presence of IL-1 beta. *Id.* at *19 (citing Sp. Mstr. Tr. at 143–45, 147–48). Moreover, the cytokines released by an inflammation in the arm would affect the whole brain rather than cause the type of focal seizures suffered by petitioner. *Id.* (citing Sp. Mstr. Tr. at 151–52). As for the timing of the seizures, Dr. Shinnar testified that the diagnosis of the onset of epilepsy was too soon after the October 2005 seizures to have been caused by them, as the usual latency period is eight to eleven years. *Id.* at *20 (citing Resp't's Ex. A at 4).

Acknowledging that the opinions of petitioner's treating physicians were entitled to weight, the Special Master nonetheless did not find them persuasive. *Holmes*, 2011 WL 2600612, at *13. Three physicians examined petitioner on the day of his initial seizures and allegedly attributed them to his vaccination. *Id.* One physician provided no rationale for that opinion, *id*. (citing Pet'r's Ex. 9 at 13); one noted that seizures were a listed side effect of the vaccine without noting the reference source (a significant omission, since the reference might have concerned a vaccine including pertussis which, unlike Td, is contraindicated for youths who have histories of seizures), *id.* & n.28 (citing Pet'r's Ex. 9 at 32; Resp't's Ex. D at 519; Sp. Mstr. Tr. at 67–70); and one erroneously thought seizures were a reaction to horse serum, which was not in fact present in the vaccine, *id.* (citing Pet'r's Ex. 9 at 21; Sp. Mstr. Tr. at 75–76). In contrast, the neurologist who diagnosed petitioner's epilepsy considered his seizures to be of "unclear etiology." *Id.* (citing Pet'r's Ex. 8 at 1). The Special Master noted that "even Dr. Kinsbourne conceded that a neurologist would be better qualified to diagnose the cause of seizures than physicians with less specialized training." *Id.* (citing Sp. Mstr. Tr. at 72).

Characterizing the case as "more a rout than a 'battle of the experts,'" the Special Master concluded that petitioner failed to establish causation under the Federal Circuit's decision in *Althen v. Sec'y of HHS*, 418 F.3d 1274 (Fed. Cir. 2005). *See Holmes*, 2011 WL 2600612, at *20. She found that petitioner's expert relied on facts that were not established and was not as qualified as respondent's expert in the areas of "diagnosing and treating febrile seizures and epilepsy." *Id*. Because of petitioner's age and the lack of any febrile illness connected with the August 18, 2005 seizures, the Special Master found the studies relied upon by Dr. Kinsbourne to be irrelevant. *Id*. Determining there was no logical connection between the facts of petitioner's case and "the limited circumstances under which complex febrile seizures can result in subsequent seizure disorders," the Special Master denied the petition for compensation. *Id.*

D. Petitioner's Motion for Review

Petitioner filed a motion for review, asking the Court to set aside the Special Master's decision on three grounds. Pet'r's Mot. for Rev. (Pet'r's Mot.) Under the *Althen* test, petitioner's burden was to show that the vaccination caused the injury by providing "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

Petitioner argued that the Special Master erred as a matter of law in applying a too stringent standard for the first prong under *Althen*; that the Special Master abused her discretion in failing to give proper weight to the treating physicians' opinions for the second prong of the *Althen* test; and that the Special Master erred by considering matters outside of the record to determine the credibility of petitioner's expert, Dr. Kinsbourne. Pet'r's Mot. at 14, 19, 22.

First, petitioner challenged the Special Master's reliance on statistical data provided by respondent's expert, Dr. Shinnar, that epilepsy-causing febrile seizures were concentrated among younger children, not adolescents. Pet'r's Mot. at 12. Petitioner argued that "statistical evidence cannot act as a preclusion to a causation theory." *Id.* (citing *Knudsen v. Sec'y of Dep't of HHS*, 35 F.3d 543, 550 (Fed. Cir. 1994)). He noted that the Special Master acknowledged that in certain circumstances a Td vaccination can cause fever, leading to seizures and ultimately seizure disorder. *Id.* (citing *Holmes*, 2011 WL 2600612, at *11). Doctor Shinnar conceded that this can happen to young children, *see Holmes*, 2011 WL 2600612, at *12, and testified that 99% of these seizures were suffered by children under age seven --- evidence that the Special Master found persuasive. *See id.* at *17. Petitioner argued that the rarity of petitioner's injury did not preclude causation and that the first prong of the *Althen* test was satisfied by showing that the Td vaccine *can* cause seizures. Pet'r's Mot. at 13–14 (citing *Capizzano v. Sec'y of HHS*, 440 F.3d 1317, 1328 (Fed. Cir. 2006)). He further contended that Dr. Shinnar did not "rule . . . out entirely" the possibility that a fourteen-year-old could suffer a seizure due to a Td vaccine, Pet'r's Mot. at 14, and that respondent's expert testified "there is not much difference between a 10 and a 14-year old," *id.* at 12 (quoting Sp. Mstr. Tr. at 173). According to petitioner, this suffices under prong one of *Althen*, and the Special Master impermissibly raised the standard for showing causation "by relying on statistical factors." *Id.* at 14.

Petitioner further argued that the Special Master erred in giving too little weight to treating physicians' opinions under the second prong of the *Althen* test. Pet'r's Mot. at 15. Citing excerpts from the medical record in which treating physicians attributed petitioner's August 18, 2005 seizures to the Td vaccine, petitioner argued that such evidence was "quite probative" under *Andreu v. v. Sec'y of HHS* 569 F.3d 1367, 1375 (Fed. Cir. 2009). *Id.* at 16 (citing Pet'r's Ex. 9 at 13, 21, 32). Though the Special Master highlighted a neurologist who found the seizures to be of "unclear etiology," petitioner argued that the neurologist did not rule out vaccination as the cause and that his opinion should be outweighed by the three other physicians' records. *Id.* at 17–18.

Finally, petitioner contended that the Special Master erred in considering the challenge to Dr. Kinsbourne's credibility that was contained in respondent's post-hearing brief. Pet'r's Mot. at 20–21. After the hearing, respondent informed the Special Master that Dr. Kinsbourne had "come under increasing scrutiny in recent years for serving as an advocate for petitioners, rather than proffering dispassionate expert opinion." *Id.* at 21 (quoting Resp't's Post-Hr'g Br. at 9). In her decision, the Special Master noted that Dr. Kinsbourne has been criticized in other cases for extrapolating from scientific studies because of faulty premises. *Holmes*, 2011 WL 2600612, at *20. Petitioner argued that the Special Master's determination of credibility based on matters outside the record was improper. Pet'r's Mot. at 22.

The Secretary filed a response to petitioner's motion for review, arguing that the Special Master properly denied compensation because petitioner failed to establish that his alleged injury was caused by the Td vaccination. Resp't's Resp. to Pet'r's Mot. for Rev. (Resp.) at 10. Respondent noted the finding that petitioner was not febrile on August 18, 2005 was enough to defeat petitioner's causation theory. *Id.* at 11. According to respondent, the evidence that no fourteen-year-old has been reported as experiencing a complex febrile seizure contradicted petitioner's medical theory of causation. Resp. at 11–12. The Secretary maintained that statistics were properly considered to show the implausibility of petitioner's theory. *Id.* at 13 (citing *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). Under the preponderant evidence standard, respondent argued, petitioner failed to establish a prima facie case, and thus respondent did not have the burden of "rul[ing] out entirely" petitioner's medical theory. *Id.* at 12.

With respect to the opinions of petitioner's treating physicians, respondent argued that the Special Master properly weighed the conflicting impressions of three physicians and Dr. Miner, the neurologist who diagnosed petitioner with epilepsy, and appropriately articulated the reasons for preferring the latter's opinion. Resp. at 14–15 (citing *Cedillo v. Sec'y of HHS*, 617 F.3d 1328, 1348 (Fed. Cir. 2010)). The Secretary noted that under the Vaccine Act, medical diagnoses do not bind special masters or judges. *Id.* at 14 (citing 42 U.S.C. § 300aa-13(b)(1)(A), (B)). Respondent also argued that treating physician testimony cannot establish causation because petitioner failed to offer a medical theory to satisfy the first prong of the *Althen* test. *Id.* at 14.

Regarding petitioner's third objection, respondent argued that the Special Master did not err in considering Dr. Kinsbourne's Vaccine Program experience and compensation for legal work. Resp. at 17. According to the Secretary, nothing barred the Special Master's consideration of Dr. Kinsbourne's pattern of erroneous extrapolation in other cases. *Id.* at 17–18. Respondent noted that petitioner had an opportunity to respond to the matters raised in the former's post-hearing brief. *Id.* at 18. And in any event, the Secretary maintained, the Special Master had given more than sufficient reasons, other than Dr. Kinsbourne's past experience, for her assessment of the reliability of petitioner's medical theory of causation. *Id.* at 19 (citing *Broekelschen v. Sec'y of HHS*, 618 F. 3d 1339, 1350 (Fed. Cir. 2010)).

The Court held oral argument on petitioner's motion. After careful consideration of the medical records, testimony, and submitted literature in the record, the decision below, and the arguments of counsel, this opinion issues.

II. DISCUSSION

A. Legal Standards

1. Court's Standard of Review of a Special Master's Decision

Under the Vaccine Act, the special master must award compensation if, "on the record as a whole," she finds "that the petitioner has demonstrated by a preponderance of the evidence" the claims of the petition. 42 U.S.C. § 300aa-13(a)(1)(A). By this same standard, the special master must find that nothing else is responsible for causing the injury. *Id*. § 300aa-13(a)(1)(B). "The

special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." *Id*. § 300aa-13(a)(1). The special master must consider all the "relevant medical and scientific evidence contained in the record," including any "diagnosis, conclusion, medical judgment, or autopsy . . . regarding the nature, causation, and aggravation of petitioner's illness, disability, injury, condition, or death" and "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." *Id*. § 300aa-13(b)(1). The Act further specifies that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court." *Id*. The special master is entrusted with evaluating the "weight to be afforded to any" of these sources of information. *Id*. A special master's "assessments of the credibility of the witnesses" and of "the relative persuasiveness of the competing medical theories of the case" are "virtually unchallengeable on appeal." *Lampe v. Sec'y of HHS*, 219 F.3d 1357, 1362 (Fed. Cir. 2000). This deference rests on the special master's "broad discretion in determining credibility because he saw the witnesses and heard the testimony," *Bradley v. Sec'y of Dep't of HHS*, 991 F.2d 1570, 1575 (Fed. Cir. 1993), and extends to assessments of expert testimony, *see Moberly v. Sec'y of HHS*, 592 F.3d 1315, 1325–26 (Fed. Cir. 2010) (*Moberly II*).

Medical records "warrant consideration as trustworthy evidence." *Cucuras v. Sec'y of the Dep't of HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). These records are "generally contemporaneous to the medical events," and "accuracy has an extra premium" because a patient's proper treatment is "hanging in the balance." *Id*. Moreover, because medical records are contemporaneous documentary evidence, conflicting oral testimony "deserves little weight." *Id*. (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947)).

In reviewing a special master's decision, the Court may "set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law." 42 U.S.C. § 300aa-12(e)(2)(B). Findings of fact are to be reviewed under the "arbitrary and capricious" standard; legal questions are to be reviewed under the "not in accordance with law" standard; and an abuse of discretion standard is used for discretionary rulings. *See Munn v. Sec'y of Dep't of HHS*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992). With respect to the arbitrary and capricious review, "no uniform definition of this standard has emerged," but it is "a highly deferential standard of review" such that "[i]f the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Hines ex rel. Sevier v. Sec'y of Dep't of HHS*, 940 F.2d 1518, 1527–28 (Fed. Cir. 1991).

2. Standard of Causation in Vaccine Cases

A special master may award compensation through an "off-table" or "causation-in-fact" case. *Pafford v. Sec'y of HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). Causation-in-fact --- the basis for the legal entitlement to compensation when a petitioner's injury is either not listed in the Vaccine Injury Table or did not occur within the time period set forth in the Table --- must be proven under two formulations adopted by the Federal Circuit. *See Id.* at 1355. The petitioner must establish that the vaccine was both a "but-for" cause of the injury and a substantial factor in causing the injury. *See Shyface v. Sec'y of HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Under a

three-part test more recently articulated by the Circuit, the petitioner must prove "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen v. Sec'y of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).[10] The petitioner bears the burden of proving causation by preponderant evidence. *See* 42 U.S.C. § 300aa-13(a)(1)(A).

A petitioner must show more than a proximate temporal relationship between the vaccination and the injury to meet his burden of showing actual causation. *Althen*, 418 F.3d at 1278; *see also Grant v. Sec'y of Dep't of HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Furthermore, "[t]here may well be a circumstance where it is found that a vaccine *can* cause the injury at issue and where the injury was temporally proximate to the vaccination, but it is illogical to conclude that the injury was actually caused by the vaccine." *Capizzano v. Sec'y of HHS*, 440 F.3d 1317, 1327 (Fed. Cir. 2006). A petitioner could meet the first and third prongs of the *Althen* test without "satisfying the second prong when medical records and medical opinions do not suggest that the vaccine caused the injury, or where the probability of coincidence or another cause prevents the claimant from proving that the vaccine caused the injury by preponderant evidence." *Id*. The sequence only has to be "'logical' and legally probable, not medically or scientifically certain," and thus can be established by "epidemiological evidence and [a] clinical picture," even "without detailed medical and scientific exposition on the biological mechanisms." *Knudsen v. Sec'y of Dep't of HHS*, 35 F.3d 543, 548–49 (Fed. Cir. 1994). Nonetheless, the Federal Circuit has stated that while "epidemiological studies are probative medical evidence relevant to causation," *Grant*, 956 F.2d at 1149, they are not necessarily dispositive. *See id*.

"The government . . . is permitted to offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case[-]in-chief." *de Bazan v. Sec'y of HHS*, 539 F.3d 1347, 1353 (Fed. Cir. 2008). If the petitioner satisfies his burden, he is entitled to compensation "unless the [government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine." *Althen*, 418 F.3d at 1278 (quoting *Knudsen*, 35 F.3d at 547) (alteration in original). But if the petitioner fails to prove causation-in-fact by a preponderance of the evidence, "alternative causation theories . . . need not be addressed." *Bradley*, 991 F.2d at 1575.

3. Standard for Evaluating Expert Testimony

In determining the reliability or sufficiency of scientific evidence of causation in a case, the special masters are guided by the factors identified by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). *See Terran v. Sec'y of HHS*, 195 F.3d 1302, 1316 (Fed. Cir. 1999); *Manville v. Sec'y of Dep't of HHS*, 63 Fed. Cl. 482, 489-91 (2004). These non-exclusive factors relate to an "assessment of whether the reasoning or methodology underlying [expert scientific] testimony is scientifically valid and of whether that reasoning or

[10] Although the Federal Circuit has described the *Althen* test as an "alternative," the very same opinion makes plain that the *Althen* "prongs must cumulatively show" that the *Shyface* standard is met. *See Pafford*, 451 F.3d at 1355.

methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. According to the Supreme Court, "a key question" to be asked of a proposed theory is "whether it can be (and has been) tested," as the scientific method entails "generating hypotheses and testing them to see if they can be falsified." *Daubert*, 509 U.S. at 593 (citations omitted). "Another pertinent consideration is whether the theory . . . has been subjected to peer review and publication." *Id.* And "[w]idespread acceptance can be an important factor" in determining the reliability of a theory, although it is not necessary. *Id.* at 594, 597. Concerning the applicability of epidemiological studies, the Supreme Court has explained: "[N]othing in . . . *Daubert* . . . requires a [trial] court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

B. The Special Master Did Not Apply An Improper Standard in Evaluating Causation.

Petitioner's first objection seems to rest on the odd notion that statistics should not be considered in determining causation. As a general proposition this cannot be correct. Statistics, after all, are in large part what epidemiology is all about, and causation can without question be based on epidemiological evidence. *See Knudsen*, 35 F.3d at 549 (explaining that "causation can be found in vaccine cases based on epidemiological evidence and the clinical picture"); *Andreu v. Sec'y of HHS*, 569 F.3d 1367, 1379–81 (Fed. Cir. 2009); *Moberly II*, 592 F.3d at 1325. Indeed, Vaccine Injury Table listings, giving rise to a presumption of causation, are often (if not always) based on such statistics. *See, e.g.*, National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table, 66 Fed. Reg. 36735, 36736 (proposed Jul. 13, 2001) (codified at 42 C.F.R. pt. 100) (explaining a table injury addition based on "epidemiological data showing a strong statistical association between the rotavirus vaccine administration and subsequent onset of intussusception").

More specifically, petitioner contends that since the Special Master accepted that the Td vaccination can cause febrile seizures and a seizure disorder for a certain segment of the population, the first prong under *Althen* is satisfied and statistics may not be considered to undermine this determination. *See* Pet'r's Mot. at 12–14. This contention suffers from two basic flaws. First, the argument about the misuse of statistics is based on a misunderstanding of the Federal Circuit's decision in *Knudsen*. *See id*. at 8, 12 (citing *Knudsen*, 35 F.3d at 550). That decision did not hold that the use of *any* statistics would be improper to overcome a prima facie causation case. Rather, it was the particular type of statistics that were being compared --- the aggregate numbers of a particular injury caused by viral infections and by a vaccination, without regard for the frequency with which each potential cause occurs. *See Knudsen*, 35 F.3d at 550. In other words, a comparison of numerators tells you nothing about the increase in relative risk due to two possible factors --- for that, you need the denominators, too.

But the statistics to which petitioner objects are relevant to determining whether a Td vaccination could *ever* be considered the cause of an adolescent's febrile seizures. The evidence that febrile seizures were not only phenomena of infancy and childhood but moreover were predominantly suffered by the very young has an obvious bearing on whether they could be the result of a vaccination administered to someone outside of that age group. *See Holmes*, 2011

WL 2600612, at *17. Doctor Shinnar testified that 99% of the children with febrile seizures in the reported literature are younger than seven years old, Sp. Mstr. Tr. at 127–28, and even in the Annegers study relied upon by Dr. Kinsbourne, 88% of the children with febrile seizures were three years old and younger, *id.* at 128; *see* Pet'r's Ex. 15 at 493, 495. Respondent's expert explained that febrile seizures are universally understood to be childhood illnesses, and the scientific studies define a child usually below age ten although occasionally as old as eleven. *See* Resp't's Ex. A at 4; Sp. Mstr. Tr. at 126–33. In all of his research he only knew of one person as old as twelve who might have suffered a febrile seizure, *Holmes*, 2011 WL 2600612, at *17; Sp. Mstr. Tr. at 132–33, and neither expert pointed to any study indicating an adolescent as old as fourteen had suffered a febrile seizure. It is no error to consider such evidence when deciding whether a febrile seizure could explain petitioner's injuries. Based on the evidence, febrile seizures for a fourteen-year-old are not "rare," as petitioner maintains, *see* Pet'r's Mot. at 13, but (at least heretofore) nonexistent.

This brings us to the second flaw in petitioner's contention. Petitioner assumes that prong one of *Althen* --- "a medical theory causally connecting the vaccination and the injury," *Althen*, 418 F.3d at 1278 --- is established when medical literature shows causation for a demographic that excludes him. But "[a] petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case." *Moberly II*, 592 F.3d at 1322. The Federal Circuit has explained, in a slightly-different context: "As a general matter, epidemiological studies are designed to reveal statistical trends only for a carefully constructed test group. Such studies provide no evidence pertinent to persons not within the parameters of the test group." *Id.* at 1324. Thus, if a study supports causation when a particular injury manifests within seven days of a vaccination, this does not require the Secretary to explain the biological reasons why an injury occurring several months later was not similarly caused. *See Moberly v. Sec'y of HHS*, 85 Fed. Cl. 571, 598 (2009) (*Moberly I*), *aff'd*, 592 F.3d at 1324. In our case, medical literature supporting causation of injuries in a different age group does not impose a burden on respondent to explain whether physiological differences between ten-year-olds and fourteen-year-olds could account for a difference in reactions to a vaccine. *Cf.* Pet'r's Mot. at 12 (arguing to the contrary). Absent epidemiological evidence to support causation, it remained the job of petitioner, not respondent, to supply a reputable medical or scientific explanation of causation.

As the Special Master amply and well explained, *see Holmes*, 2011 WL 2600612, at *11–12, whether the Td vaccination can generally cause fever, febrile seizures, and seizure disorder are not the relevant questions to establish the first prong of *Althen* in petitioner's case. Considering the testimony and literature supplied by both experts, she concluded that the medical theory by which the vaccination can cause the injuries must take into account such factors as the age of the patient, the severity of the fever and the duration of the seizures. *Id.* The statistics (or, more accurately, the lack of any) showing febrile seizures suffered by members of petitioner's age group were but one consideration in determining that petitioner had failed to prove causation-in-fact.

The Special Master summarized petitioner's causal chain as the vaccination causing a febrile response, the fever causing complex febrile seizures, and the complex febrile seizures causing petitioner to have a seizure disorder which was later diagnosed as epilepsy. *Holmes*,

2011 WL 2600612, at *13. Petitioner's expert conceded his opinion was based on the August 18, 2005 seizures having been febrile. Sp. Mstr. Tr. at 57–59. But the Special Master found there was no reliable evidence of a fever connected with the first seizure. *Holmes*, 2011 WL 2600612, at *9. Doctor Kinsbourne mistakenly believed that petitioner's mother "stated that he felt hot," Pet'r's Ex. 14 at 1, when she was not even home at the time of his first seizure. *Holmes*, 2011 WL 2600612, at *9 (citing Pet'r's Ex. 9 at 31; Sp. Mstr. Tr. at 27–28). The recorded temperature in the treating physician's narrative and the ER records showed petitioner had a temperature of 97.6° after his first seizure, *see* Pet. Ex. 7 at 1, 3; Pet. Ex. 9 at 31–32, and Doctor Kinsbourne conceded that a 97.6° temperature was normal, Sp. Mstr. Tr. at 62. And while petitioner's temperature was recorded as being higher in connection with his second seizure, the Special Master reasonably found that seizure not to be febrile, as petitioner's temperature was recorded at its peak to be 100° when taken orally, and 99.9° rectally --- both short of the 101° threshold for a febrile seizure. *Holmes*, 2011 WL 2600612, at *9–10, *17 (citing, *inter alia*, Pet'r's Ex. 9 at 6; Resp't's Exs. A1 at 1122, A6 at 1743).[11] Concerning this seizure, Dr. Kinsbourne misread the medical record showing an oral temperature of 100° as an axillary temperature and had erroneously translated it to an oral temperature of 101°, which he had testified would meet the minimum threshold for most studies on febrile seizures. Sp. Mstr. Tr. at 63–64; *see* Pet'r's Ex. 9 at 6. On top of all this, the Special Master reasonably determined that there was no evidence to support the presence of a febrile illness suffered by petitioner in proximity to the August 18, 2005 seizures. *Holmes*, 2011 WL 2600612, at *17.[12]

Thus, petitioner's medical theory of causation suffered from problems other than petitioner being the wrong age to experience febrile seizures.[13] The Special Master also found that the fever necessary for any reliable version of this theory was not demonstrated by the record evidence --- a finding which petitioner does not seem to challenge. She also reasonably determined that respondent's expert provided "compelling testimony undercutting" much of the rest of petitioner's theory of causation, *id.* at *18, including that the August 18, 2005 seizures were too short in duration to have caused petitioner's epilepsy, *id.*; that IL-1 beta was unlikely to cause focal seizures and that sufficient amounts of it were not evidenced, *id.* at *19; and that the onset of petitioner's epilepsy was too soon after the August 18, 2005 seizures to be their result, *id.* at *20. The Special Master did not subject petitioner's case to an improperly stringent standard of causation; rather, she appropriately applied the correct standards to find that

[11] The Special Master also noted that "[t]he lowest temperature used in any study of febrile seizures and their sequelae is 100.4°, a higher temperature than any that [petitioner] experienced." *Holmes*, 2011 WL 2600612, at *17 (citing Sp. Mstr. Tr. at 133–34).

[12] The Court notes that the EMS report concerning the second seizure indicated that petitioner's temperature was normal at the time. Pet'r's Ex. 7 at 4.

[13] Without elaboration or explanation, petitioner suggests that the Micromedex evaluations satisfy prong one of *Althen*. *See* Pet'r's Mot. at 14. But the Special Master rationally explained why such reports are unpersuasive, *see Holmes*, 2011 WL 2600612, at *13 n.31, discussing Dr. Shinnar's testimony and other evidence that the Td vaccine is recommended for adolescents with seizure disorders. *Id.* at *18 (citing Sp. Mstr. Tr. at 139–42; Resp't's Ex. D at 519).

petitioner failed to demonstrate a reliable medical theory that was logically connected to his circumstances. Petitioner's first objection is accordingly rejected.

C. The Special Master did Not Abuse her Discretion in her Evaluation of the Treating Physicians' Opinions

Disagreeing with the Special Master's determinations of the probative value of some of the notations in the medical records made by treating physicians, petitioner maintains that the Special Master abused her discretion. *See* Pet'r's Mot. at 15–19. Petitioner argues that the second prong of *Althen* was satisfied by these medical opinions. *Id.* at 18. But "Federal Circuit precedent makes it evident that the first prong of *Althen* must be proven before the opinions of treating physicians may clinch causation under the other prongs." *Langland v. Sec'y of HHS*, 109 Fed. Cl. 421, 438 (2013) (citing *Andreu*, 569 F.3d at 1375). While there might be circumstances in which a treating physician's opinion itself provides an adequate basis to find *Althen* prong one satisfied, for instance by containing a reliable theory explaining how the vaccine caused the injury in question, *see id*. at 438–39, the opinions relied upon by petitioner are not that sort. Indeed, petitioner insists that he "satisfies the first prong of the Althen test without reliance upon the treating physicians' reports," Pet'r's Mot. at 18.

Although the failure to establish a medical theory satisfying the first prong of *Althen* might well make the objection regarding the second prong academic, the Court nevertheless has reviewed this objection and found it wanting. While the statements of treating physicians can be "quite probative" of the prong two "logical sequence of cause and effect," *see Andreu*, 569 F.3d at 1375 (internal citations and quotations omitted), the Vaccine Act makes plain that such statements must be considered but "shall not be binding on the special master or the court," and mandates that the "entire record" must be considered in evaluating their weight, 42 U.S.C. § 300aa-13(b)(1). Thus, even diagnoses of causation may be outweighed by other evidence. *See Moberly I*, 85 Fed. Cl. at 604 (explaining that such a diagnosis "would, at the least, require the Special Master to explain how other evidence outweighed these medical records"). The Court agrees with respondent that "'[t]he Special Master clearly articulated why [she] declined to afford significant weight to the notations made by [some of petitioner's] treating physicians,' and accordingly committed no error." Resp. at 15 (quoting *Cedillo*, 617 F.3d at 1348).

Petitioner focuses on three records, two of which were from the emergency room, generated on the date of his initial seizures --- containing the opinions of Drs. Schultz, Llobet and Yang. Pet'r's Mot. at 16 (citing Pet'r's Ex. 9 at 13, 21, 32). The Special Master admitted that these opinions were "entitled to weight," *Holmes*, 2011 WL 2600612, at *13 (citing *Andreu*, 569 F. 3d at 1375), and she referenced them, cited to them, and gave reasonable explanations for why she did not consider them probative. Doctor Yang wrote concerning petitioner that "[g]iven his recent history of a tetanus vaccine, he could well have had a reaction towards the vaccine components, probably horse serum." Pet'r's Ex. 9 at 21. This opinion was found erroneous, as petitioner's expert acknowledged that the Td vaccine does not contain horse serum. *Holmes*, 2011 WL 2600612, at *13 (citing Sp. Mstr. Tr. at 75–76). Doctor Llobet recorded the impression "[s]eizure, status post tetanus shot," and wrote that she "had looked up the tetanus adverse reactions and one of them it listed is seizures." Pet'r's Ex. 9 at 32. The Special Master found it significant that Dr. Llobet did not identify the reference she consulted, as the tetanus

vaccination is often combined with one for pertussis, and evidence in the record indicated that adolescents with a history of seizures may be administered the former but not the latter. *Holmes*, 2011 WL 2600612, at *13 n.28 (citing Resp't's Ex. D at 519). And Dr. Schultz wrote the impression "[s]eizure by history, most likely secondary to tetanus toxoid immunization," Pet'r's Ex. 9 at 13, which the Special Master accurately noted as "providing no rationale," *Holmes*, 2011 WL 2600612, at *13.

Of the three medical reports, then, one was demonstrably wrong and the other two were found to lack a sufficient explanation. The substantive quality (and quantity) of the diagnoses was very far from that in *Andreu*, for instance, in which the treating physicians took the witness stand and explained their opinions. *See Andreu*, 569 F.3d at 1376. Moreover, the Special Master properly considered the entire record in determining the amount of weight these records should receive. She determined that the opinions rendered on the day of petitioner's initial seizures were "countered" by the opinion of the neurologist who subsequently treated petitioner. *Holmes*, 2011 WL 2600612, at *13. Petitioner's expert "conceded that a neurologist would be better qualified to diagnose the cause of seizures than physicians with less specialized training." *Id*. (citing Sp. Mstr. Tr. at 72). And the neurologist in question, Dr. Miner, while noting the temporal proximity of the Td vaccination and the initial seizures, nevertheless determined that the seizures were of "unclear etiology." *Id*. (quoting Pet'r's Ex. 8 at 1). The Special Master did not abuse her discretion in evaluating the medical records, but instead provided a careful, thorough and reasoned explanation for the weight she gave them, supported by reference to other parts of the record. No error was committed in this evaluation.[14]

D. The Special Master did Not Act Improperly in Determining the Credibility of Experts

In petitioner's third objection, he contends that the Special Master acted improperly by basing her determination of expert credibility on matters that were outside the record. Pet'r's Mot. at 19–22. Petitioner complains that the Special Master cited two decisions in which Dr. Kinsbourne had been criticized, and argues that respondent unfairly included a similar discussion (concerning other cases) in the government's post-hearing brief. *Id.* at 20–21 (citing Resp't's Post-Hr'g Br. at 9–11; *Holmes*, 2011 WL 2600612, at *20).[15] The Court finds this objection lacks merit.

"Under the Vaccine Act, Special Masters are accorded great deference in determining the credibility and reliability of expert witnesses," and a court will not disturb such determinations

[14] Petitioner also references three excerpts from his medical records, created after the initial seizures, which he contends establish that he has suffered from encephalopathy since receiving the vaccination. Pet'r's Mot. at 15 (citing Pet'r's Exs. 8 at 26, 10 at 7, and 11 at 10). None of these records discuss the vaccination as the cause of his injuries.

[15] The Special Master's mere mention, in a footnote, of the percentage of petitioner's expert's income that derives from legal matters, is wrongly characterized by petitioner as a "criticism." *See* Pet'r's Mot. at 20; *Holmes*, 2011 WL 2600612, at *2 n.9. In any event, this statement was based on evidence in the record, *see* Sp. Mstr. Tr. at 57, and thus has no relevance to the third objection.

when "the Special Master clearly articulated [her] reasons for discrediting [an] expert's opinion." *Cedillo*, 617 F.3d at 1347. The Federal Circuit has explained:

> it is not . . . the role of this court to reweigh the factual evidence, or to assess whether the special master correctly evaluated the evidence. And of course we do not examine the probative value of the evidence or the credibility of the witnesses. These are all matters within the purview of the fact finder.

Munn v. Sec'y of Dep't of HHS, 970 F.2d 863, 871 (Fed. Cir. 1992).

The Court finds that the Special Master did not err as a matter of law in her credibility determination, nor did she improperly base her decision on matters outside the record. Rather, she painstakingly and in great detail explained the reasons why she found respondent's expert to be more credible.

First, there were the problems with petitioner's expert's testimony. Doctor Kinsbourne's causation theory rested on petitioner having had a fever at the time of both seizures on August 18, 2005, such that the seizures met the definition of complex febrile seizures, but this opinion was based on errors and unsupported by the factual evidence in the record. *See Holmes*, 2011 WL 2600612, at *8–9, *16. For example, as discussed above, the Special Master expressed concern that Dr. Kinsbourne based his opinion of fever during the first seizure on the EMS description of skin temperature and on a "mistaken impression" that petitioner's mother was present, *id*. at *8 (citing Pet'r's Ex. 7 at 1, 3; Pet'r's Ex. 14 at 1), yet Dr. Kinsbourne overlooked or discounted the fact that the emergency room recorded James's temperature as 97.6°, which he later conceded was a normal temperature, *id*. at *9 (citing Pet'r's Ex. 14 at 1; Pet'r's Ex 9 at 28; Sp. Mstr. Tr. at 62). Additionally, because Dr. Kinsbourne based his opinion mainly on the record pertaining to petitioner's *second* seizure, *id*. at *9 (citing Pet'r's' Ex. 18 at 1), the Special Master considered his error particularly significant when he mistakenly read the report as showing petitioner had an axillary temperature of 100°, *id*. at *9–10. The Special Master explains that Dr. Kinsbourne "misread the medical records in forming his conclusion that [petitioner] was febrile at the time of the first seizure and had an 'elevated' temperature at the time of the second," and "[t]his mistake alone justifies rejecting Dr. Kinsbourne's opinion." *Id*. at *16.

The Special Master primarily found fault with the chain of causation offered by Dr. Kinsbourne, explaining that even if she were to accept Dr. Kinsbourne's proposed theory, "petitioner's case fails, because the factual predicate for Dr. Kinsbourne's opinions is lacking." *Holmes*, 2011 WL 2600612, at *12. The Special Master evaluated each element of Dr. Kinsbourne's causation theory, and compared the evidence Dr. Kinsbourne relied upon to the factual evidence in the record. *Id*. She repeated her concern that Dr. Kinsbourne testified in the hearing that without the presence of fever he would not present the same opinion about causation. *Id*. at *14 (citing Sp. Mstr. Tr. at 57–59). Because the facts did not support that petitioner had a fever at the time of the first seizure and only supported a possible slight fever at the time of the second, the Special Master stated that Dr. Kinsbourne's testimony of petitioner's fever causing the initial seizures "is an exceedingly weak link in Dr. Kinsbourne's causal chain." *Id*. The Special Master also thought Dr. Kinsbourne relied on circular reasoning when he opined

that the initial seizures were themselves evidence of a lowered seizure threshold but did not offer any other evidence that petitioner had a lower seizure threshold. *Id*.

Second, the Special Master fully explained why she found Dr. Shinnar's opinions more credible than Dr. Kinsbourne's. She determined that Dr. Shinnar's opinions were "careful, nuanced, and supported by the medical literature," and "reflected his considerable experience in studying and treating seizure disorders." *Holmes*, 2011 WL 2600612, at *16. She found Dr. Shinnar's opinion regarding the effect of febrile seizures to be more reliable because of his "considerable expertise in the diagnosis and treatment of such disorders, his research credentials in the field, and the medical literature filed by both parties." *Id*. at *12. This is a reasonable basis on which to make a credibility determination. *See Terran*, 195 F.3d at 1316. The Special Master also found it important that Dr. Shinnar differentiated febrile seizures from epilepsy, which Dr. Kinsbourne did not do, and that his refutation of Dr. Kinsbourne's diagnosis of complex febrile seizures conformed to the facts in the record. *Holmes*, 2011 WL 2600612, at *16. The Special Master noted that Dr. Shinnar offered other testimony which undermined petitioner's theory of causation, such as presenting credible medical literature to disprove the possibility of Td vaccinations causing seizures in fourteen-year-olds, and to show that short febrile seizures do not cause epilepsy. *Id*. at *18–19.

After carefully considering and discussing in great detail the testimony of both experts, *see id.* at *13–20, the Special Master concluded that "[m]ost of the 'facts' upon which [petitioner's expert] relied were not established;" that "he either misread or misinterpreted the medical records"; and that he "lacked the research qualifications and clinical expertise in diagnosing and treating febrile seizures and epilepsy to prevail over an opposing expert with truly impressive qualifications in these areas." *Id.* at *20. She then mentioned in passing that petitioner's expert "has been criticized in the past for extrapolating from studies of the DPT vaccine to the DTaP vaccine." *Holmes*, 2011 WL 2600612, at *20 (citing *Tembenis v. Sec'y of Dep't of HHS*, No. 03-2820V, 2010 WL 5164324, at *8 n.9 (Fed. Cl. Spec. Mstr. Nov. 29, 2010) (citing *Simon v. v. Sec'y of Dep't of HHS*, No. 05-941V, 2007 WL 1772062, at *7 (Fed. Cl. Spec. Mstr. June 1, 2007))). This was followed by a similar description of the shortcomings of petitioner's expert's testimony in this case, as he was found to have "extrapolated from studies of infants and young children, whom he acknowledged have brains that are very different from older children and adolescents ([Sp. Mstr.] Tr. at 106), to apply their findings and conclusions to a seizure disorder in an adolescent." *Id.* It is clear that the basis for this description was the Special Master's assessment of the expert opinions presented in this case.[16] She was not deducing that petitioner's expert must have erroneously extrapolated here because he did it elsewhere. Even assuming that the consideration of an expert witness's reputation and credibility as determined in other cases would be improper in determining the credibility of his testimony --- a proposition which petitioner fails to support --- no such thing was done by the

[16] Judicial officers may, of course, properly consider whether an expert's opinion suffered from "too great an analytical gap between the data and the opinion proffered." *Gen. Elec. Co.*, 522 U.S. at 146.

Special Master below. Accordingly, petitioner's third objection is rejected, as the Special Master did not commit legal error in making her credibility determinations.[17]

III. CONCLUSION

Petitioner's motion for review is **DENIED** and the decision of the Special Master is **SUSTAINED**. The Clerk of Court is directed to enter judgment for respondent.

IT IS SO ORDERED.

s/ Victor J. Wolski

VICTOR J. WOLSKI
Judge

[17] Moreover, it does not appear that the criticisms of petitioner's expert that were recited in respondent's post-hearing brief had any bearing on the Special Master's credibility assessment. In any event, petitioner had the opportunity to address them in a reply paper and chose not to do so. *See* Pet'r's Post-Hr'g Reply Mem. at 1–2.